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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,411	07/07/2005	Michael Cowley	4040.001000	6101

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EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,411	COWLEY ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-17,31,32,34,51-53,67-69 and 77-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-17,31,32,34,51-53,67-69 and 77-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment filed on September 9, 2008. Claims 2-8, 18-30, 33, 35-50, 54-66, and 70-76 have been cancelled. New claims 77-80 have been added.

2. Claims 1, 9-17, 31, 32, 34, 51-53, 67-69, and 77-80 are currently pending and are under examination.

3. Any rejections not recited below are hereby withdrawn.

Withdrawal of Rejections

4. The rejection of claim 34, 52 and 55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claims.

5. The rejection of claim 69 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, new matter rejection is withdrawn based on the amendment to the claims.

6. The rejection of claims 1-3, 5, 7-35, and 37-43, 51-65, and 67-74 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the amendment to the claims.

7. The rejection of claims 1-43 and 51-75 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing hunger, decreasing calorie intake, increasing satiety, does not reasonably provide enablement for preventing weight gain or preventing obesity is withdrawn based on the amendment to remove the word preventing.

8. The rejection of claims 1-3, 5-43, 51-65, and 67-74 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising administering a PYY or PYY(3-36) to a subject, does not reasonably provide enablement for all agonist of PYY is withdrawn based on the amendment to the claims to remove reference to all agonists.

9. The rejection of claims 1-16, 18, 21-31, 33-68, 70, and 74-76 under 35 U.S.C. 102(e) as being anticipated by Pittner et al. U.S. 20020141985 (filing date December 14, 2001) is withdrawn based on the remarks and the file history in copending application 10/490,776 (particularly the Notice of Allowance dated July 28, 2008).

10. The rejection of claims 1, 32, and 73 under 35 U.S.C. 103(a) as being unpatentable over Pittner et al. U.S. 20020141985 (filing date December 14, 2001) in view of Yang Y., *"Emerging therapeutic targets in obesity: new approaches to controlling body weight,"* Emerging Therapeutic Targets , 3(1), pages 165-176 (1999) is withdrawn based on the remarks and the file history in copending application 10/490,776 (particularly the Notice of Allowance dated July 28, 2008).

11. The rejection of claims 17, 19, 20, 71 and 72 under 35 U.S.C. 103(a) as being unpatentable over Pittner et al. U.S. 20020141985 (filing date December 14, 2001).In paragraphs [0057] and [0085] Pittner et al. teach that animals were fasted for 1 day, or 20 hours, respectively, prior to administration is withdrawn based on the remarks and the file history in copending application 10/490,776 (particularly the Notice of Allowance dated July 28, 2008).

Pending Rejections

Double Patenting

12. Claims 1, 11, 12, 14-17, 31, 32, 51-53, 67-69, and 77-80 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,459,432 (U.S.S.N 10/490,776). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are of overlapping scope. The claims of the issued U.S. Patent are drawn to a method of decreasing calorie intake, food intake or appetite in a human subject in need thereof, comprising peripherally administering prior to a meal to said subject PYY_{3-36} (SEQ ID NO: 334) in a dose of from 5 to 100 nmoles per 70 to 75 kg body weight of said subject (see claims 1-18).

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1, 9-17, 31, 32, 34, 51-53, 67-69, and 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claims 1, 15, and 80 are rejected for referring to a peptide sequence without identifying the peptide by amino acid sequence identifier. What is the structure or species of the PYY_{3-36} peptide? Suggest identifying the peptide by SEQ ID NO:.

16. In claim 14, it is unclear how intracisternal is peripheral administration. The cisternae are located in the central nervous system.

17. In claim 51, it is unclear if the dose is per kg or per 70 to 75 kg body weight?

18. Claims dependent on claims 1, 15, and 80 are rejected for failing to cure the indefiniteness.

Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peripheral administration that is intravenous, which does not require typically a high dose, does not reasonably provide enablement for any species of peripheral administration including subcutaneous, oral, and transdermal, which typically require a higher dose to provide an effective concentration of a peptide upon delivery. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are rejected because of undue experimentation to practice the claimed method for the genus of any peripheral route of administration for the concentrations contemplated for the method claimed. The undue experimentation arises due to the degradation of peptide based on the differing routes of administration. The low concentrations being claimed in the method would require undue experimentation to develop a means of administering e.g. by transdermal administration (see also Interview summary of co-pending application 10/490,776 dated 4/23/2008).

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP § 2164.06(a). References should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required.

1) The nature of the invention: the instant claims are directed to a method for decreasing caloric intake, food intake or appetite in a human subject in need thereof, which comprises peripherally administering prior to a meal to said subject PYY_{3-36} from about 45 to 135 pmoles per kilogram body weight of the subject.

3) The predictability or unpredictability of the art: & 6) The quantity of experimentation necessary: & 7.) The state of the prior art: the prior art has shown a large quantity of experimentation is often necessary to overcome the unpredictable development of peptide pharmaceuticals to decrease appetite in a human subject need thereof. In addition, Applicant's remarks in the instant application filed September 9, 2008 state that Pittner (previously cited) shows the unexpected weight increase upon administration of low doses of PYY (see page 13 last sentence).

There would be a large quantity of experimentation necessary to determine what dosage routes can be used to administer the correct dosage for the intended effect of decreasing calorie intake, food intake or appetite.

8.) Level of skill in the art: the level of skill in this art is high, at least that of a doctoral scientist with several years of experience in the art.

The issue in this application is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan, and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "… scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art…". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skill in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)*. Therefore, absent direction/guidance one of skill in the art would not be able to

practice the claimed invention commensurate in scope with the claims. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Conclusion

21. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 3, 2009
/ANAND U DESAI/
Primary Examiner, Art Unit 1656